REMARKS

Status of the Application and Claims

Claims 1-9, 12, 14-16, and 19-23 are currently under examination. Claim 10 has been canceled in the current amendment. Claims 11, 13, 17, and 18 have been canceled in a prior amendment. Remaining claims are amended herein and support of these amendments is discussed below.

Withdrawn Rejections

Applicants acknowledge with appreciation the Office's withdrawal of the following rejections:

The rejection of claims 11 and 13 under 35 U.S.C. § 112, second paragraph;

The rejection of claims 1-2, 4-10, 12, 14-16, and 19-21 under U.S.C. § 112, second paragraph;

The rejection of claims 11 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Jehanli et al. (1996) and Cole et al., (US Patent 4,859,612) as applied to claims 1, 10, and 12 above, and further in view of Esser.

Each issue raised in the Office Action dated December 28, 2004, is now discussed below in the order they were raised.

35 U.S.C. § 112 , Second Paragraph, Rejection of Claim 3

On page 3, paragraph 1 of the Office Action, claim 3 is rejected as reciting improper alternative expressions.

Claim 3, as amended, recites the term "or" in describing the alternative limitations provided. In addition, claim 6 is amended to recite proper alternative expression, and claims 2, 8, 15, and 21 are amended to include a comma before the term "or." Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 103(a) Rejection Based on Jehanli et al. in view of Cole et al.

On page 3, paragraph 3 of the Office Action, the Office has maintained the rejection of claims 1-3, 5-7, 9-10, 12, 14-16, and 19-23 under 35 U.S.C. § 103 (a) based on Jehanli et al. (1996) in view of Cole et al. (US Patent 4,859,612).

According to the Office, it would have required no more than routine skill to incorporate the gold labeled antibody of Cole et al. into the immunoassay taught by Jehanli et al. to "modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains an enzyme labeled antibody and is adapted for receiving said fluid." Applicants respectively traverse.

As set forth in M.P.E.P. § 2143, in order "to establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teaching . . . . Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

The Office has failed to establish a *prima facie* case of obviousness because one of ordinary skill in the art would not have been motivated to combine the teachings of Jehanli et al. and Cole et al. Jehanli et al. teaches an ELISA system, in which the drug contained in a biological fluid sample competes with drug-conjugate coated onto a microtitre well to bind to

drug-specific antibodies added to the microtitre well. There is absolutely no teaching or suggestion in Jehanli et al. about a labeled antibody. Cole et al., on the other hand, describes mainly a sandwich mode immunoassay system, in which the to-be-detected drug reacts with both antibody associated with solid phase particles and antibody associated with metal particles to form a sandwich. One essential element of the Cole et al. system, the solid phase particles coated with antibody, is not present at all in the Jehanli et al. system. As a result, it would be far from obvious for one of ordinary skill in the art to apply the antibody-coated gold particles from Cole et al. to Jehanli et al., of which the mechanism of immunoassay is different. Moreover, in the only example disclosed by Cole et al. that utilizes competitive assay mode instead of sandwich mode, namely Example IV(b) (col. 14, lines 47-59), the gold particles were not coated with antibody, but with drug-conjugate. It would be hard to imagine why one of ordinary skill in the art, inspired by Example IV(b) of Cole et al., would want to painstakingly replace the drug-conjugate on the gold particles with antibody, remove the antibody-coated solid phase particles completely from the system, and apply the drug-conjugate stripped from the gold particles to a solid wall in a microtitre well, in order to reach the combination alleged by the Office.

Further, claim 1, as amended, now recites that the first part "consists of a stick." The support of this limitation can be found on page 4, lines 28-31 of the application. The limitation is incorporated into claims 2-3, 5-7, 9, 12, 14-16, and 19-23 through their dependency upon claim 1. Claim 10 has been canceled. Claims 16, 19, 22, and 23 are amended to reflect the limitations as set forth in Claim 1. Because neither Jehanli et al., Cole et al., or the combination of the two references, teaches or suggests the limitation as amended, a *prima facie* case of obviousness can not be established.

Applicants further wish to point out that the "microtitre strips" in Jehanli et al. consists of microtitre wells on a microtitre plate. Although the Office mistakenly referred to the microtitre strips as "sticks" (Office Action dated April 08, 2004, page 6, line 17), the microtitre strips as used in Jehanli et al. neither anticipates nor renders obvious the use of sticks as defined in the present application.

On page 4, paragraph 2 of the Office Action, the Office alleged that there is no structural difference between the conjugate drug and labeled antibody of the prior art and those instantly claimed, and therefore the determination of the drug within 5 to 30 minutes can be achieved through the prior art. The argument is presumably based on page 9, paragraph 1 of the Office Action dated April 8, 2004, which stated that Jehanli et al. teaches that color development takes about 30 minutes. Applicants respectively traverse.

First of all, there is structural difference between the drug immunoassay in the prior art and those instantly claimed. The present invention involves a stick, an element that is not present in the prior art. Further, although Jehanli et al. discloses a color development time of 30 minutes (page 915, right column, lines 11-12), the color development step follows a 1 hour incubation step (page 915, right column, lines 6-7). The total contact time between the drug conjugate and the antibody is at least 90 minutes, well exceeding the 30 minutes limit as instantly claimed. Finally, Applicants point out that the method disclosed in Example IV(b) of Cole et al. requires 4 minutes for the beads to mix and shake and approximated 30 minutes to settle, again making the total contact time greater than 30 minutes as instantly claimed. Therefore, it would not have been obvious for one of ordinary skill of the art to combine the two references and reach the instantly claimed invention.

Applicants assert that the Office failed to establish a *prima facie* case of obviousness for at least the reasons stated above. Accordingly, Applicants respectfully request the rejection of claims 1-3, 5-7, 9-10, 12, 14-16, and 19-23 be withdrawn.

35 U.S.C. § 103(a) Rejection Based on Jehanli et al. and Cole et al. in view of de Jaeger et al.

On page 6, paragraph 3 of the Office Action, the Office has maintained the rejection of claim 4 under 35 U.S.C. § 103 (a) based on Jehanli et al. (1996) and Cole et al. (US Patent 4,859,612), and further in view of de Jaeger et al. (US Patent 4,837,168).

Applicants respectfully request that the rejection of claim 4 under 35 U.S.C. § 103 (a) be withdrawn in light of the deficiencies noted in the references for the *prima facie* case of obviousness for claims 1-3, 5-7, 9-10, 12, 14-16, and 19-23 combined with de Jaeger et al., as the deficiencies are not cured by de Jaeger et al.

35 U.S.C. § 103(a) Rejection Based on Jehanli et al. and Cole et al. in view of Baker et al.

On page 2, paragraph 2 of the Office Action, the Office has maintained the rejection of claim 8 under 35 U.S.C. § 103 (a) based on Jehanli et al. (1996) and Cole et al. (US Patent 4,859,612), and further in view of Baker et al. (US Patent 5,624,806).

Applicants respectfully request that the rejection of claim 4 under 35 U.S.C. § 103 (a) be withdrawn in light of the deficiencies noted in the references for the *prima facie* case of obviousness for claims 1-3, 5-7, 9-10, 12, 14-16, and 19-23 combined with Baker et al., as the deficiencies are not cured by Baker et al.

In view of the foregoing remarks, Applicants request the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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